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Notice of Allowability	Application No.	Applicant(s)	
	10/712,679	PATEL, HARSHAD	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and terminal disclaimer filed on July 27, 2004.
2. ☒ The allowed claim(s) is/are 21-33 (renumbered 1-13).
3. ☒ The drawings filed on 12 November 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carol LaSalle on August 16, 2004.

On line 4 of claim 21, the abbreviation "PT" was changed to -prothrombin (PT)--. On line 5 of claim 21, the phrase "said control reaction area" was changed to -said first control reaction area--. On lines 7-8 of claim 21, the phrase "wherein said upper limit comprises a value" was deleted and replaced by the word -is--. On line 8 of claim 21, the phrase "PT result for assay reaction area PT results" was changed to -PT results--.

On line 2 of claim 25, the phrase "said control reaction area" was changed to -said first control reaction area--.

On line 4 of claim 27, the abbreviation "PT" was changed to -prothrombin (PT)--. On line 5 of claim 27, the phrase "said control reaction area" was changed to -said second control reaction area--. On line 8 of claim 27, the phrase "said first section" was changed to -said first portion--.

On line 4 of claim 29, the abbreviation "PT" was changed to -prothrombin (PT)--. On line 5 of claim 29, the phrase "said control reaction area" was changed to -said first control reaction area--. On lines 5-6 of claim 29, the phrase "an upper limit and lower limit" was

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changed to –a first upper limit and a first lower limit--. On line 6 of claim 29, the phrase “wherein said upper limit” was changed to –wherein said first upper limit--. On lines 7-8 of claim 29, the phrase “wherein said upper limit comprises a value” was deleted and replaced by the word –is--. On line 8 of claim 29, the phrase “PT result for assay reaction area PT results” was changed to –PT results--. On lines 9-10 of claim 29, the phrase “said lower limit and said upper limit” was changed to –said first lower limit and said first upper limit--. On line 11 of claim 29, the phrase “said control reaction area” was changed to –said second control reaction area--. On lines 11-12 of claim 29, the phrase “an upper limit and a lower limit” was changed to –a second upper limit and a second lower limit--. On line 12 of claim 29, the phrase “said upper limit” was changed to –said second upper limit--. On line 13 of claim 29, the phrase “said lower limit” was changed to –said second lower limit--. On line 14 of claim 29, the phrase “said first section” was changed to –said first portion--. On line 15 of claim 29, the phrase “said upper limit and said lower limit” was changed to –said second upper limit and said second lower limit-. Lines 16-18 of claim 29 were deleted.

2. The following is an examiner’s statement of reasons for allowance: Application serial no. 10/712,679 is being allowed in view of the appropriately filed terminal disclaimer received on July 27, 2004.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 17, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700